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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,815

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Lukas Eisermann

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04/28/2009

Medtronic

Attn: Noreen C. Johnson, IP Legal Department

2600 Sofamor Danek Drive

Memphis, TN 38132

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/773,815	Applicant(s) EISERMANN ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/09 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lateral walls that have received screws for a connection rod and also have slots prepared for a intervertebral prosthesis must be shown or the feature(s) canceled from the claim(s). The drawings are noted by the Examiner to show the features separately, but not one drawing was said to be described to illustrate the claimed combination. The Examiner notes the claims had recited the connection rod was removed and the claims now do not include such a recitation thus, if the claimed combination is possible with the apparatus as claimed it must be shown. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitations that the laterally inserted screws (insertion members) areand not engaging a pedicle of the vertebrae or spaced from the pedicle was not found in the written disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The preparation of a vertebral lateral wall to have slots formed therein that has insertion members (screws) placed in the same lateral walls such that the walls are not compromised is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The Examiner notes the recited references by the Applicant to specific drawings (Figs. 2,3a,3b,7,8,10,19) and the written description of paragraphs 72-119. However, the Examiner fails to see where any of the recited disclosure describe a vertebrae designed to receive such a combination of the two corrective apparatus features inserted in the vertebrae and any particular drawing illustrating a lateral wall that has both corrective apparatus in combination together. What the Examiner has reviewed by the Applicant all describe individual apparatus intended to be used in separate methods of corrective repair, not in combination.

Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate

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member or rod *in combination* with insertion of an implant **between** the vertebrae. How is this possible? If the lateral slots are formed for the implant, there is no safe area in the lateral sidewall then to receive the bone screws for the elongate rod or vice versa. The claims recite both apparatus (implant and correction rod system) are inserted or used laterally, thus it is not possible to perform this with both sets of apparatus used laterally as claimed in claim 36. Regarding claim 37, the disclosure describes the insertion of the apparatus described above, but fails to describe removal of the apparatus.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12,13,17,21,31-35,38 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Laurain (5108395). Laurain discloses a method for correcting a spinal condition having incorrect curvature by removing an intervertebral disc, col. 1, lines 25-30, col. 6, lines 49-52. The surgeon then inserts laterally into the sidewall of the vertebrae, clamps and bone screws, (Figs. 1,9) and then a connecting member **6** is joined to engage the clamps to span between the vertebrae. Laurain discloses that a rotating force is applied to the connecting member to rotate the vertebrae relative to one another, col. 3, lines 4-16, col. 7, lines 18-21,47-52. The Examiner interprets a "spondylosed relationship" as a incorrectly curved spine. With respect to claim 13, the examiner is interpreting the claimed elements "prosthetic joint" in this way: an object between the vertebrae in the

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“joint” space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. Thus, since Laurain illustrates (Fig. 8,9) a prosthetic graft **G** in the joint space, it can be considered a “prosthetic joint”. Regarding claim 21, it is inherent that the surgeon uses a wrench to rotate the screws having hex head sections. A surgeon cannot use his hands to do this. With respect to claim 33, it is known in the art that grafts promote fusion. Regarding claim 34, it is inherent that the graft will permit some articulation or motion (which can be compression) between the vertebrae. Since placement of the elongate member **6** is on the lateral side of the vertebrae, it can be considered a lateral approach. However, in the alternative, Laurain fails to explicitly state the method corrects spondylolisthesis. Since Laurain discloses correcting an incorrectly curved spine, it would have been obvious to one of ordinary skill in the art to use the method of Laurain in correcting a patient with spondylolisthesis since it would involve adjusting an incorrect curvature and the results would be predictable in moving the vertebrae in a more straight alignment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain ‘395. Laurain is explained supra. However, Laurain fails to disclose the implant is inserted laterally. It would have been obvious to one of ordinary skill in the art to insert

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the implant while performing the surgery in the patient to place the implant laterally into the patient before placing the elongate member onto the screws since this would not require any more incisions in the patient since the lateral side has been exposed. It is common sense that a surgeon would minimize the incisions a patient would require such that the healing is kept to a minimum.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Jacobson et al. (5382248) and Conchy et al. (6749612). Laurain is explained supra. However, Laurain fails to disclose disengaging the elongated member from the insertion members and removing it along with the insertion members from the sidewall of the vertebrae. Conchy et al. teach (Fig. 8) that rods **2,3** spanning between vertebrae can be removed, col. 6, lines 28-30. Jacobson et al. teach that bone screws can become loose and broken to require removal, col. 6, lines 16-26, col. 12, lines 11,12,35-45. It would have been obvious to one of ordinary skill in the art to remove an incorrect elongate member as taught by Conchy et al. and broken screws as taught by Jacobson et al. from the vertebrae inserted by the method of Laurain such that problems with the correction apparatus can be corrected if necessary.

Claims 12,13,17,20,21,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (5591165) in view of Conchy et al. (6749612) and Kapp et al. (4554914). Jackson discloses (Figs. 9A-C) a spondylolisthesis correction system including bone screws laterally inserted into first and second lateral sidewalls of the vertebrae and a connecting member or rod **1** is spanned between the vertebrae. Jackson also discloses the connecting member is rotated (Fig. 9B) and discloses the

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system is used to correct spinal deformities by rotation from a lateral approach since it is done in the sagittal plane, col. 10, lines 6-10, 19-41. However, Jackson fails to disclose that the insertion members do not engage pedicles or are spaced from the pedicles and that the spinal disc would need to be removed or to place an implant between the vertebrae. Conchy et al. teach (Fig. 8) that the insertion members and corrected member rod are to be used laterally in the sidewall of vertebrae spaced from and not engaging the pedicle. It would be an obvious expedient to space the insertion members from the pedicles to be placed in the sidewall or lateral wall of the vertebrae since it is a larger bony mass of tissue and has more structural support for the screw. Kapp et al. teach (Fig. 1) that a prosthesis is to be inserted into the intervertebral space that also used a bone screw and connector member that spans the vertebrae. Jackson additionally teaches that first an intervertebral disc is removed to define a space for an implant, col. 2, lines 46-48, col. 4, lines 17-20. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary or degenerative as taught by Kapp et al. when performing the procedure of Jackson and inserting bone screws spaced from and not in the pedicle as taught by Conchy et al. and the connecting member laterally on the vertebrae such that no further damage or painful conditions continue and the degenerative area is stabilized. Regarding claim 13, the Examiner is not giving any special meaning to the term "joint" to limit the prosthesis since no structure is defined in the claim and is being read into the claim. Thus since, Kapp's device can move it is a prosthetic "joint". With respect to claim 21, it would have been an obvious expedient to use a rotatable wrench to rotate the connecting member as

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such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 14-16,39,40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Conchy et al. '612 and Kapp et al. '914 as applied to claims 13,31 above, and further in view of Marnay (5314477). Jackson as modified by Conchy et al. and Kapp et al. is explained supra. However, Jackson in view of Conchy et al. and Kapp et al. fail to disclose laterally forming slots or elongate slots in the vertebrae for laterally extending keels on a bone substitute implant inserted between the vertebrae. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) the bone substitute implant maintains space between the vertebrae. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally-extending keels of a bone substitute implant and modify the device of Kapp incorporated into the method of Jackson as modified with Conchy et al. such that the vertebral engaging members that are part of the joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and not be displaced.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson '165 in view of Conchy et al. '612 and Kapp et al. '914 as applied to claim 17 above, and further in view of Wagner et al. (6030389). Jackson in view of Conchy et al. and Kapp et al. is explained supra. However, Jackson as modified by Conchy et al. and

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Kapp fail to disclose the type of screws used in the surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the spinal implant of Jackson in view of Conchy et al. and Kapp et al. such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Response to Arguments

Applicant is advised that the response has raised doubts as to whether the combination is actually illustrated in the drawings because in the last response it was acknowledged that while both corrective apparatus (screws with a rod and a spinal implant) are shown in the drawings, it was possible that one may be removed (the rod). However, since Applicant responded by cancelling the limitation of claim 40 because it was new matter, the Examiner's conclusion was correct in that it was not clear that both are actually used together.

Applicant's arguments filed 1/29/09 have been fully considered but they are not persuasive. Applicant has presented arguments that the written disclosure describes the method of correcting spondylolisthesis where screws are used with a connection rod and then has a spinal implant with keels inserted in the lateral walls that already had been corrected with the screws and rod. The Examiner failed to find a specific recitation discussing the lateral walls receiving both the screws and keels of a spinal implant. It is

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noted that Applicant had mentioned prior to the action above drawings and specification recitation in an attempt to show support for combination, of which the Examiner was not persuaded and then had added a claim (40) with a recitation to remove the rod to enable the spinal implant to be inserted. The Examiner thought that while such a procedure may be possible, such claim language must be supported by sufficient disclosure and it was determined there was no support for such a clause in the written disclosure and that has prompted the Examiner to justify that the Applicant has not properly described the combination. It is the Examiner's position that the disclosure describes various procedures and apparatus to adjust the vertebrae, but if the two contrasting apparatus were intended to be used together it should have been made clear in the written disclosure and the drawings.

In response to applicant's argument that Laurain discloses a method for correcting kyphoses and not spondylolisthesis, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Laurain can be said to disclose all the claimed method steps and thus can be said to provide the ability to correct spondylolisthesis. Applicant alleges the Laurain apparatus is not rotated. However, the Examiner respectfully disagrees, as Figs. 6 and 7 illustrate that rotating steps cause the change of curvature of the spine to be corrected to a more straight alignment. Clearly a rotational force is applied to cause the alignment to move in a more straight configuration of the vertebrae.

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Applicant's arguments with respect to claims rejected over Jackson as modified with the other cited prior art have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738